

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

WYETH HOLDINGS CORPORATION,	)	
WYETH-AYERST LEDERLE LLC, and	)	
WYETH LLC,	)	
	)	
Plaintiffs and Counterclaim-	)	
Defendants,	)	
	)	
v.	)	Civ. Action No. 09-955-LPS-CJB
	)	
SANDOZ, INC.,	)	
	)	
Defendant and	)	
Counterclaim-Plaintiff.	)	

**REPORT AND RECOMMENDATION REGARDING PLAINTIFFS' MOTION TO  
DISMISS SANDOZ'S FOURTH COUNTERCLAIM AND TO STRIKE SANDOZ'S  
FOURTH AFFIRMATIVE DEFENSE DIRECTED TO INEQUITABLE CONDUCT<sup>1</sup>**

Pending before the Court in this patent case is a motion filed pursuant to Fed. R. Civ. P. 12(b)(6) and 12(f) by Wyeth Holdings Corporation, Wyeth-Ayerst Lederle LLC, and Wyeth LLC (collectively, "Wyeth" or "Plaintiffs") seeking dismissal of the Fourth Counterclaim and Fourth Affirmative Defense of Sandoz, Inc. ("motion to dismiss"). (D.I. 64) Sandoz opposes Wyeth's motion to dismiss.

For the reasons that follow, I recommend that the Court DENY Wyeth's motion.

**I. BACKGROUND**

**A. Procedural History**

This is a patent case arising from Sandoz's filing of Abbreviated New Drug Application

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<sup>1</sup> Absent unanimous consent of the parties to the jurisdiction of a United States Magistrate Judge, a Magistrate Judge's authority as to the resolution of a motion to dismiss pursuant to Rule 12(b)(6) is limited to making a Report and Recommendation to the District Court. 28 U.S.C. § 636(b)(1)(B); D. Del. LR 72.1(a)(3).

("ANDA") No. 91-620 with the United States Food and Drug Administration ("FDA"). Sandoz's ANDA seeks to market an injectable form of tigecycline, an antibiotic that Wyeth currently markets under the brand name Tygacil®. (D.I. 1 at ¶ 10) Wyeth first filed suit against Sandoz on December 11, 2009. (D.I. 1) On September 7, 2011, Wyeth filed an Amended and Supplemental Complaint ("Amended Complaint") that reflects its current allegations against Sandoz. (D.I. 48) Wyeth's Amended Complaint alleges that Sandoz's generic tigecycline product infringes at least one valid claim of U.S. Reissue Patent No. 40,183 and U.S. Patent No. 7,879,828 ("the '828 patent") (collectively, "the patents-in-suit") and seeks a permanent injunction barring Sandoz from manufacturing, using, selling, or offering to sell in the United States, or importing into the United States, any drug product that infringes a valid claim of the patents-in-suit. (*See* D.I. 48)

Sandoz has stipulated that by submitting ANDA No. 91-620, it has committed an act of infringement under 35 U.S.C. § 271(e)(2), and has further stipulated that the commercial manufacture, use, and/or sale of its generic tigecycline antibacterial products would infringe the asserted claims of the patents-in-suit, if any of those claims are found valid and enforceable. (D.I. 62 at 5, ¶ 16; 6, ¶ 24) While conceding infringement, Sandoz challenges the validity of both of the patents-in-suit (*id.* at 7), and asserts that the '828 patent is unenforceable based upon several acts of inequitable conduct (*id.* at 11–17).

Sandoz first asserted that inequitable conduct should bar enforcement of the '828 patent on October 21, 2011, two days after the close of fact discovery. (D.I. 62; D.I. 68 at 3) In lieu of answering Sandoz's counterclaim for inequitable conduct, Wyeth moved to dismiss (and to strike the accompanying affirmative defense of unenforceability based on inequitable conduct). (D.I.

64) Sandoz timely opposed (D.I. 68), and Wyeth's motion to dismiss was fully briefed on December 8, 2011 (D.I. 70). The Court heard oral argument on Wyeth's motion to dismiss on January 31, 2012. (D.I. 85)

**B. Sandoz's Inequitable Conduct Defense**

The '828 patent was issued to Plaintiff Wyeth LLC on February 1, 2011, and is based on Application No. 11/374,330 ("the '330 application"). It is entitled "Tigecycline Compositions and Methods of Preparation," and lists three individuals (Mahdi B. Fawzi, Tianmin Zhu, and Syed M. Shah) as inventors. ('828 patent at 1) Although the title of the '828 patent refers to "Methods of Prepar[ing]" tigecycline, all of the '828 patent claims are directed to compositions that include tigecycline, lactose, and an acid. (D.I. 65 at 1, 3)

Tigecycline is a well-known antibiotic in the tetracycline family. ('828 patent at col. 1:23–25; col. 2:55–65) It is a particularly effective intravenous treatment against certain strains of drug-resistant bacteria. (*Id.* at col. 1:24–29, 45–47) Tigecycline is typically dissolved in water and then freeze-dried or "lyophilized" into a powder form before being shipped to end users, such as hospital pharmacies. (*Id.* at col. 1:55–63) Prior to being administered to patients, the powder is mixed with saline or another form of diluent and placed into intravenous bags for delivery. (*Id.* at col. 1:66–2:7)

During this process, tigecycline is subject to two countervailing degradative pathways. First, tigecycline is susceptible to rapid oxidation in solution form, which typically occurs at a slightly basic pH (about 7.8). (*Id.* at col. 2:26–35) To avoid this oxidative degradation, the pH of the solution can be lowered by adding an acid or buffer. (*Id.* at col. 2:44–48) However, lowering the pH triggers a second degradative process, known as epimerization. (*Id.* at col.

2:48–50) Under acidic conditions, the standard "*cis*" form of tigecycline is converted into the "*trans*" isomer. This epimerized product is non-toxic, but also exhibits low antibacterial efficacy. (*Id.* at col. 3:16–21) Thus, according to the '828 patent, there was a need to develop a composition that minimizes both the propensity of tigecycline to oxidize and its tendency to epimerize. (*Id.* at col. 3:62–65) It is through the addition of a carbohydrate (such as lactose) that a stable balance against the countervailing degradation pathways is achieved. (*Id.* at col. 4:49–59)

The addition of lactose and the accompanying acidic pH conditions claimed in the '828 patent are at the heart of Sandoz's inequitable conduct defense.<sup>2</sup> This defense spans more than nine pages, and refers to several exhibits, including a PowerPoint presentation given by Wyeth to the U.S. Patent & Trademark Office ("PTO"); redacted tigecycline stabilization data; patents and prior art references; prosecution history excerpts; and a declaration from Mr. Christian Ofslager, a Section Head at Wyeth.<sup>3</sup> (*See* D.I. 62 & exs. 1–6) The claims of the '330 application were rejected during prosecution by the PTO Examiner in light of a U.S. patent publication. (*Id.* at 8, ¶ 6) The Examiner argued that this publication (hereinafter referred to as the "Testa" reference)

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<sup>2</sup> Sandoz asserts inequitable conduct (and explains the basis for its allegations) in the Fourth Affirmative Defense in its Amended Answer. (D.I. 62 at 8–17) Sandoz asserts an identical counterclaim based upon the same facts and law. (*Id.* at 22) For ease of reference, Sandoz's Fourth Affirmative Defense and Fourth Counterclaim are collectively referred to as Sandoz's "inequitable conduct defense."

<sup>3</sup> Although the Court is resolving a motion to dismiss, not a summary judgment motion, the Court may consider not only the allegations in Sandoz's Amended Answer, but also any "exhibits attached to the [pleading] and matters of public record." *Collins & Aikman Corp. v. Stockman*, Civ. No. 07-265-SLR-LPS, 2010 WL 184074, at \*3 (D. Del. Jan. 19, 2010) (quoting *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)).

disclosed the combination of tigecycline and excipients, including lactose. (*Id.* at 8, ¶ 7)

Moreover, in the Examiner's view, it would have been obvious to a person of ordinary skill in the relevant art to use the teachings of Testa to introduce lactose into an acidic, lyophilized solution of tigecycline to stabilize the solution against degradation. (*Id.*) The Examiner further rejected the applicants' argument that the claims were nonobvious because the claimed combination unexpectedly stabilized tigecycline; instead, he found that any improvement in stability was "minimal" at best, and "that the claimed compositions demonstrated no unexpected results."<sup>4</sup> (*Id.* at 8, ¶ 8)

In response, the applicants filed a request for continued examination, and thereafter made presentations to the Examiner aimed at overcoming his rejection. Sandoz contends that as part of this process, Wyeth made certain claims to the Examiner that amounted to "affirmative misrepresentations of material fact." (*Id.* at 8, ¶ 4) Sandoz cites three means through which the PTO allegedly received false and misleading information from Wyeth, as part of its response to the Examiner's final rejection: (1) during the Examiner's post-rejection interview of certain Wyeth representatives on September 16, 2010; (2) through data disclosed in the '828 patent and internal Wyeth data submitted to the PTO; and (3) in the October 5, 2010 declaration submitted to the PTO by Mr. Ofslager, who also participated in the September 16, 2010 interview. (*See*

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<sup>4</sup> "Unexpected results" are a secondary consideration of non-obviousness that can be used to overcome a rejection by the PTO. *See, e.g., Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1291–92 (Fed. Cir. 2011) (Prost, C.J., dissenting) ("The Supreme Court has instructed us that four factors should be used in assessing obviousness: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) *secondary considerations* such as commercial success, *unexpected results*, and long-felt need.") (emphasis added). "[S]econdary considerations, when present, must be considered in determining obviousness." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000).

D.I. 62 at 9–17, ¶¶ 9–32)

In these presentations, Wyeth allegedly made two primary arguments: (1) the prior art, as exemplified by a European patent ("the '277 reference") "taught away" from the use of lactose to stabilize tigecycline in light of other information; and (2) the addition of lactose to an acidic solution of tigecycline led to significant and unexpectedly stable results, citing experimental data that was included in the text of the '330 application or submitted to the FDA. (*See id.*) Sandoz contends that in making these statements, Wyeth's representatives misrepresented the teachings of the prior art, overstated the stabilizing effects of lactose, and omitted key information regarding experimental error rate and discrepancies in data. (*Id.*) According to Sandoz, these actions deceived the Examiner, who issued the '828 patent due to Wyeth's claims of "unexpected results" and other representations made by Wyeth during prosecution. (*Id.* at 16, ¶ 30)

## **II. STANDARD OF REVIEW**

### **A. Motion to Dismiss Under Rule 12(b)(6)**

Prior to 2007, district courts were permitted to dismiss a complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) only if "it appear[ed] beyond doubt that the plaintiff [could] prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957). The Supreme Court, concerned that this "no set of facts" language could be read to suggest that "a wholly conclusory statement of claim would survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some set of [undisclosed] facts to support recovery," rejected that test in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). *Id.* at 561 (internal quotations and citations omitted). A plaintiff is now required to plead sufficient "factual matter (taken as true) to suggest" liability for

the alleged misconduct. *Id.* at 556. Such a complaint must include "more than labels and conclusions" or the "formulaic recitation of the elements of a cause of action," but need only provide "enough facts to state a claim to relief that is plausible on its face." *Id.* at 555, 570.

In *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937 (2009), the Supreme Court extended these standards to all civil complaints. *Id.* at 1953. Notably, the *Iqbal* Court held that a claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 1949. The plausibility standard is not akin to a "probability requirement, but it asks for more than a sheer possibility that a defendant acted unlawfully." *Id.* (internal quotation marks omitted).

After *Twombly* and *Iqbal*, district courts in the Third Circuit faced with a motion to dismiss pursuant to Rule 12(b)(6) should perform a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009). First, the district court should separate the factual and legal elements of a claim, accepting any well-pleaded facts as true, but disregarding any legal conclusions. *Id.* Second, the district court must "determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Iqbal*, 129 S.Ct. at 1950). Determining whether a claim is plausible is "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Id.* (quoting *Iqbal*, 129 S.Ct. at 1949).

In so doing, the court must "construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler*, 578 F.3d at 210 (citing *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (internal quotations omitted)); *see also Erickson v. Pardus*, 551 U.S. 89,

94 (2007) ("[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.") As such, a well-pleaded complaint may not be dismissed simply because "it strikes a savvy judge that actual proof of [the alleged] facts is improbable, and that a recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (internal quotations omitted).

#### **B. Motion to Strike Under Rule 12(f)**

As noted above, Sandoz has asserted inequitable conduct in two substantively identical but procedurally distinct forms—as both a counterclaim and an affirmative defense. Rule 12(b)(6) does not offer a mechanism for dismissing an affirmative defense, and instead refers only to "claim[s]." Fed. R. Civ. P. 12(b)(6). However, pursuant to Rule 12(f), the Court "may strike from a pleading any insufficient defense." Fed. R. Civ. P. 12(f). This rule has been used in this jurisdiction to strike affirmative defenses where a party has failed to state a corresponding claim upon which relief can be granted. *See, e.g., Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, Civ. No. 08-309-JJF-LPS, 2009 WL 4928024, at \*8–10 (Dec. 18, 2009). There is no dispute that Sandoz's inequitable conduct counterclaim and affirmative defense "rise[] or fall[]" together. (D.I. 68 at 4)

#### **C. Pleading Inequitable Conduct Under Rule 9(b)**

An individual associated with the filing and prosecution of a patent application commits inequitable conduct when he or she (1) makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO; (2) with the specific intent to deceive the PTO. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). If both of these elements—materiality and intent—are proven



by clear and convincing evidence, this equitable defense bars enforcement of a patent.

*Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). Although inequitable conduct is conceptually broader than fraud, any such allegations must be pled in accordance with Rule 9(b), which requires that "the circumstances constituting fraud or mistake shall be stated with particularity." *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1342, 1344 (Fed. Cir. 2003) (quoting Fed. R. Civ. P. 9(b)).

In *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009), the Federal Circuit established the standard for evaluating the sufficiency of inequitable conduct allegations.<sup>5</sup> *Exergen* held that:

[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO. Moreover, although 'knowledge' and 'intent' may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

575 F.3d at 1328–29.

However, roughly eighteen months after the Federal Circuit's decision in *Exergen*, an *en banc* Federal Circuit altered and clarified the elements for proving inequitable conduct in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011). Unlike *Exergen*, which specifically outlined the requirements for *pleading* inequitable conduct, *Therasense*

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<sup>5</sup> Although *Exergen* concerned a motion for leave to amend a pleading to assert an inequitable conduct defense, its standards are also used to assess the sufficiency of a pleading that is challenged in a motion to dismiss. See *In re BP Lubricants USA, Inc.*, 637 F.3d 1307, 1311 (Fed. Cir. 2011).

involved the review of a district court decision as to inequitable conduct made after a bench trial. *Id.* at 1285. In *Therasense*, the Federal Circuit retained the two-pronged construct requiring a showing of both materiality and intent to deceive. However, in various ways, it elected to "tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." *Therasense*, 649 F.3d at 1290.

For example, the *Therasense* Court overruled a separate series of decisions that placed the materiality and intent prongs on a "sliding scale," in which a weak showing of intent could be found sufficient based on a strong showing of materiality, or vice versa. *Id.* at 1288. In addition, as to the first prong regarding materiality, *Therasense* held that absent evidence of "affirmative egregious misconduct," this prong requires a "but-for" showing. *Id.* at 1291–92. In other words, the party making an inequitable conduct claim must show that but for an omission or misrepresentation by the patent applicant, the PTO would not have allowed a patent claim to issue. *Id.*

As for the intent prong, *Therasense* expressly overruled a series of decisions holding that if a misrepresentation or omission at issue amounted to gross negligence or mere negligence, this would be sufficient to satisfy the intent prong; instead, a deliberate decision to make the misrepresentation or omission would be required. 649 F.3d at 1287–90. Lastly, the Federal Circuit re-emphasized its prior holding that although "a district court may infer intent from indirect and circumstantial evidence . . . , to meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Id.* at 1290 (quoting *Star Scientific*, 537 F.3d at 1366).

### III. DISCUSSION

#### A. Applicable Standard Governing Inequitable Conduct Pleadings

In its opening brief, Wyeth claims that, under the tightened materiality standards announced in *Therasense*, "a pleading of inequitable conduct requires factual allegations that make it plausible that but for the alleged omission, the Examiner would not have issued the patent." (D.I. 65 at 8) Wyeth argues Sandoz has not met this burden. Moreover, as to the intent prong, Wyeth repeatedly asserted that Sandoz's inequitable conduct defense should be dismissed because "Sandoz did not plead any facts that would allow the Court to conclude that *the single most reasonable inference* from the applicants' alleged conduct is that the applicants had the specific intent to deceive the PTO." (D.I. 65 at 2 (emphasis added); *see also id.* at 8, 10) Citing *Therasense*, Wyeth argued that unless the Court finds that intent to deceive is the "single most reasonable inference" that can be drawn from the facts alleged in Sandoz's pleading, *Therasense* compels dismissal of Sandoz's inequitable conduct defense. (*Id.* at 9–11)

In response, Sandoz concedes that at the pleading stage, in light of *Therasense*, it must allege facts allowing for the reasonable inference of "but-for" materiality.<sup>6</sup> (D.I. 68 at 10–12) The Court agrees that *Therasense* impacted the pleading standards for inequitable conduct claims in this way. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F. Supp. 2d 409, 432 (E.D. Va. 2011).

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<sup>6</sup> Prior to *Therasense*, the Federal Circuit had adhered to less rigid standards for demonstrating materiality, often rooted in the PTO's Rule 56. *Therasense*, 649 F.3d at 1294; *see also* 37 C.F.R. § 1.56 (1977) (a reference is material "if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent"). The *Therasense* Court concluded that the current version of Rule 56 sets too "low [a] bar" because "anything bearing any relation to obviousness could be found material." *Id.* at 1294–95.

However, Sandoz argues that Wyeth has "attempt[ed] to conflate the holdings of *Therasense* and *Exergen* to impose an insurmountable pleading bar for allegations of inequitable conduct" as to the intent prong. (D.I. 68 at 9) According to Sandoz, the *Therasense* Court did not disturb the applicable pleading standard in this way. It urges the Court to reject Wyeth's formulation of the intent prong, and instead use the standard articulated in *Exergen*: whether deceptive intent could be "reasonably infer[red]" from the facts as pled. (*Id.*)

At oral argument, despite the argument made in its opening brief, Wyeth withdrew its assertion that *Therasense*'s "single most reasonable inference" standard has any bearing on the Court's analysis at the pleading stage. (D.I. 85 at 9–10) However, because Wyeth has otherwise argued that Sandoz has not met the threshold showing of intent required by *Twombly*, *Iqbal* and *Exergen*, I am required to determine what the contours of that standard are. For this reason, and in light of the parties' previously divergent positions, the Court will briefly analyze how the "single most reasonable inference" language from *Therasense* should be reconciled with the "reasonable inference" directives from *Exergen*.

Several district courts have recently confronted this question and have reached different conclusions. On one end of the spectrum, the District of South Dakota denied a motion for leave to file an amended answer alleging inequitable conduct because "there [were] multiple reasonable inferences that may be drawn" from the facts alleged in the proposed inequitable conduct pleading. *Hansen Mfg. Corp. v. Enduro Sys., Inc.*, No. CIV. 11–4030, 2011 WL 5526627, at \*4 (D.S.D. Nov. 14, 2011). This conclusion derives from the *Hansen* Court's determination that "*Therasense* tightened the *standard for pleading* so that specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Id.*

(emphasis added) (internal quotation marks and citation omitted); *see also Quest Software, Inc. v. Centrifly Corp.*, No. 2:10-CV-859 TS, 2011 WL 5508820, at \*2–3 (D. Utah Nov. 9, 2011) (denying defendant's motion for leave to file amended answer including inequitable conduct claim in part because "the allegations do not reveal that the intent to deceive is the most reasonable inference to be drawn from the evidence").

Other courts have held that the "single most reasonable inference" standard applies to at least some extent in the pleading context. For instance, the Eastern District of Virginia determined that "*Exergen* still states the correct elements required for pleading inequitable conduct after *Therasense*," and that a party is not required at the pleading stage "to meet the clear and convincing evidence standard that applies on the merits." *Pfizer Inc.*, 803 F. Supp. 2d at 432. However, the *Pfizer* Court concluded that in light of *Therasense*, "a party must make an initial showing from which it may be plausibly inferred that . . . the intent to deceive is the single most likely explanation for the non-disclosure [of but-for material information]." *Id*; *accord VDF FutureCeuticals, Inc. v. Sandwich Isles Trading Co.*, Civ. No. 11–00288 ACK–RLP, 2011 WL 6820122, at \*6 (D. Haw. Dec. 27, 2011) (dismissing an inequitable conduct counterclaim where the allegations pled did not "give rise to a plausible inference that the intent to deceive was the single most likely explanation" for the alleged conduct). While the *Pfizer* and *VDF* Courts did not take as rigid a view as did *Hansen*, they nonetheless held that the "single most reasonable" rubric has been engrafted onto the inequitable conduct pleading standard from *Exergen*.

I disagree with the conclusions reached by these courts. Instead, for the three reasons set forth below, I believe that in order to adequately plead the intent prong of an inequitable conduct defense, the claimant need only allege facts from which the Court could *reasonably infer* that the

patent applicant made a deliberate decision to deceive the PTO.

First, the Federal Circuit explains in *Therasense* that the "single most reasonable inference" requirement is an *evidentiary* standard that must be satisfied at the proof stage, not a pleading standard. The Federal Circuit notes that "to meet the clear and convincing *evidence* standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the *evidence*. . . . Indeed, the *evidence* must be sufficient to require a finding of deceitful intent in light of all the circumstances." *Therasense*, 649 F.3d at 1290 (emphasis added) (internal quotation marks omitted). This statement is couched strictly in terms of the ultimate evidentiary analysis, in which a district court determines whether under a heightened standard of proof (the clear and convincing evidence standard), deceptive intent is the single most reasonable inference to be drawn. This form of analysis clearly contrasts with the pleading stage analysis required by *Iqbal*, which asks whether, taking all of the alleged facts as true, the Court can draw the "reasonable inference" that a party is liable for the claimed misconduct, such that the claim is "plausible." *Iqbal*, 129 S.Ct. at 1949. After all, courts "do not inquire whether a plaintiff will ultimately prevail when considering a motion to dismiss, only whether the plaintiff is *entitled to offer evidence to support his or her claims*." *Grier v. Klem*, 591 F.3d 672, 676 (3d Cir. 2010) (emphasis added). Moreover, at the pleading stage, a court does not (and cannot) review "all of the circumstances" at play in a case, as the *Therasense* "single most reasonable inference" inquiry requires. 649 F.3d at 1290. Instead, a court assessing the sufficiency of a pleading looks only to a narrow category of materials (the pleading and any attached exhibits) provided only by one side (the party or parties asserting the inequitable conduct claim).

Second, in *Exergen*, the Federal Circuit appeared to specifically indicate that the "single

most reasonable inference" analysis was a separate inquiry from that used to examine whether inequitable conduct is well-pled. After holding that a party must plead facts from which a court can "reasonably infer" that material information was misrepresented or withheld with the specific intent to deceive the PTO, the *Exergen* Court noted how this pleading standard differs from the applicable standard of proof first articulated in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365–66 (Fed. Cir. 2008):

In contrast to the pleading stage, to prevail on the merits, the accused infringer must prove both materiality and intent by clear and convincing evidence. *See Star Scientific*, 537 F.3d at 1365. *Whereas an inference of deceptive intent must be reasonable and drawn from a pleading's allegations of underlying fact to satisfy Rule 9(b), this inference must be the 'single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.'* *Id.* at 1366.

*Exergen*, 575 F.3d at 1329 n.5 (emphasis added). To read *Therasense* as disturbing this well-established dichotomy would be to collapse inequitable conduct into a mini-trial on the pleadings, and to ignore the clear holdings from both *Star Scientific* and *Exergen*. The Court finds no language in *Therasense* to support such an outcome, particularly given that "*Therasense* did not address inequitable conduct at the motion to dismiss stage and did not discuss leave to amend." *Oracle Corp. v. DrugLogic, Inc.*, No. C 11-00910 JCS, 2011 WL 3443889, at \*13 (N.D. Cal. Aug. 8, 2011).

Third, this reading is corroborated by the Federal Circuit's own post-*Therasense* case law. In *Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337 (Fed. Cir. 2011), the Federal Circuit stated that "[a] charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff's complaint recites facts from which the court may *reasonably infer* that a specific individual both knew of invalidating information that was

withheld from the PTO and withheld that information with a specific intent to deceive the PTO." *Id.* at 1350 (citing *Exergen* and *Therasense*) (emphasis added). Although this statement does not definitively resolve the issue (in part because it refers only to non-disclosure of information, as opposed to misrepresentation of material information, as alleged by Sandoz here), it strongly suggests that Sandoz need only set forth facts from which deceptive intent can be reasonably inferred.<sup>7</sup> *Accord Human Genome Sciences, Inc. v. Genentech, Inc.*, Case No. 2:11-cv-6519-MRP (JEMx), slip op. at 6 (C.D. Cal. Dec. 9, 2011) (considering *Therasense* and *Exergen* and concluding that "[i]n order to survive dismissal [of an inequitable conduct claim], the accused infringer must allege facts from which it is plausible that the applicant had an intent to deceive," and need not demonstrate that deceptive intent is "the most reasonable inference").

In light of these considerations, and hewing closely to the guidance of the Federal Circuit, the Court will assess whether the facts as pled give rise to a reasonable inference that material information was misrepresented with the specific intent (i.e., as the result of a deliberate decision) to deceive the PTO.

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<sup>7</sup> In this District, only a single written opinion resolving a motion to dismiss an inequitable conduct claim has issued since *Therasense*. See *Softview LLC v. Apple Inc.*, Civil Action No. 10-389-LPS, 2011 WL 4571793 (D. Del. Sept. 30, 2011). In *Softview*, this Court granted a motion to dismiss and strike an inequitable conduct claim and defense where the defendants' "theory [of inequitable conduct] [was] based on a mere disagreement with . . . prosecution counsel as to whether certain amendments impermissibly added 'new matter.'" *Id.* at \*1. In granting the motion to dismiss and strike, the Court found that any such "disagreement does not give rise to a *reasonable inference* that prosecution counsel" knew that he was adding new matter and intended to deceive the PTO by so doing. *Id.* (emphasis added). This language suggests that a "reasonable inference" of specific intent is sufficient to state a claim for inequitable conduct at the pleading stage. However, the parties in *Softview* did not raise the question as to what impact (if any) *Therasense* had on this question, as *Therasense* was not yet issued at the time that the parties submitted their briefs.



**B. Inequitable Conduct Has Been Pled With Sufficient Particularity Under the Applicable Standard**

**1. Materiality Prong—Misrepresentation of Material Fact**

Inequitable conduct allegations typically center on the failure of a patent applicant to disclose relevant prior art. *See, e.g., Genentech, Inc. v. Trustees of the Univ. of Pa.*, No. 10-CV-02037-LHK, 2011 WL 1936136, at \*7 (N.D. Cal. May 20, 2011). In this case, however, there is no allegation of a failure to disclose a prior art reference. Instead, Sandoz alleges that Wyeth's representatives misrepresented the teachings of the prior art in a manner that would be recognized as false by a person of ordinary skill in the art, and also submitted incomplete, misleading, and internally inconsistent empirical data relating to epimer formation in experimental solutions of tigecycline. (D.I. 62)

As an initial matter, the Court finds that Sandoz has properly and specifically identified the "who, what, where, when, and how" of the alleged material misrepresentations. *See generally Aerocrine AB v. Apieron, Inc.*, Civ No. 08-787-LPS, 2010 WL 1225090, at \*9 (D. Del. Mar. 30, 2010). The "who" refers to three individuals who played a role in the prosecution of the '330 application: Mr. Ofslager, a Wyeth employee involved in the development of Tygacil® who submitted a declaration to the PTO and attended the interview with the Examiner; and Ian Liu and David Joran, two Wyeth attorneys who prosecuted the '330 application and also attended the Examiner interview. (D.I. 62 at 9, ¶ 9) The "what" in this case refers to the alleged misrepresentations regarding the state of prior art (including the '277 reference, which Wyeth allegedly used as a "straw man"), (*id.* at 10, ¶ 13), and the tigecycline stabilization data that was submitted to and discussed with the PTO. The "when" implicates at least two separate dates on

which misrepresentations were allegedly made: (1) at the examiner interview on September 16, 2010; and (2) the submission of the Ofslager declaration on October 5, 2010. (*Id.* at 9, ¶ 9; 12, ¶ 19) The "where"—meaning where in the prior art and other documents submitted the allegedly material information is found—is detailed in the Amended Answer, which lists each piece of information that was (or was not, but allegedly should have been) part of the asserted misrepresentations. (*See id.* at 9–16) As for the "how" element—how a reasonable examiner would have used the information allegedly concealed or falsified by Wyeth's representatives—Sandoz describes two such ways. First, by falsely asserting that a person of ordinary skill in the art would understand that the possible stabilization mechanisms discussed in the cited references "could not work for tigecycline," Wyeth was able to improperly overcome the obviousness rejection. (*Id.* at 10, ¶ 12) Second, by arguing that the Wyeth stability data established "unexpected results," Wyeth convinced the Examiner that secondary considerations of non-obviousness should overcome his rejection of the '330 application. (*Id.* at 10, ¶ 15) According to Sandoz, these data were flawed. (*Id.* at 10–15)

In its briefs, Wyeth alleges that Sandoz's allegations fall short of the requirements of the materiality prong in two primary respects. First, Wyeth asserts that Sandoz has not made the requisite showing of but-for materiality, because it "never alleged that 'the PTO would not have allowed a claim had [the Examiner] been aware' of the alleged 'critical information [that Wyeth's representatives did not share with the Examiner].'" (D.I. 65 at 12) However, Sandoz *did* explicitly allege but-for materiality. After listing the various types of alleged misrepresentations made to the Examiner by Wyeth representatives, Sandoz asserted: "Thus, the '828 patent would not have been issued *but for* [Wyeth's] deceptive and erroneous representations to the [PTO]."

(D.I. 62 at 16, ¶ 30 (emphasis added)) Moreover, Sandoz alleged that because the Examiner specifically acknowledged and cited many of the statements made by Wyeth's representatives when listing the Reasons for Allowance of the '828 patent, but-for materiality is a reasonable inference. (*Id.*) Therefore, contrary to Wyeth's assertion, the allegation of but-for materiality was squarely made.

Moreover, that allegation is legally sufficient because the underlying facts allow the Court to draw the reasonable inference that the '828 patent would not have issued but for the alleged misrepresentations. Those alleged misrepresentations were made during the September 16, 2010 Examiner interview (in which Wyeth's representatives were attempting to overcome the Examiner's earlier rejection of the '330 application) and in the October 5, 2010 Ofslager declaration (a document submitted for the specific purpose of convincing the Examiner that the invention at issue was non-obvious). Moreover, the Examiner repeatedly cited the data provided in the declaration as the primary reason for his allowance of the patent. (D.I. 62, ex. 6 at 3 ("Applicant has overcome this prima facie case of obviousness by providing secondary considerations, in the form of unexpected results, as highlighted by the Ofslager Declaration below.")) The clear nexus between the alleged misrepresentations, the circumstances in which they were made, and the resulting impact they had on the Examiner's decision, leads to a reasonable inference of but-for materiality.<sup>8</sup>

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<sup>8</sup> Cf. *Pollin Patent Licensing, LLC v. Capital One Auto Fin., Inc.*, No. 1:10-CV-07420, 2011 WL 5118891, at \*4 (N.D. Ill. Oct. 25, 2011) (finding allegations of materiality in inequitable conduct claim sufficient to permit leave to amend to add claim, as counterclaimant had alleged that the patent application would not have been granted if the information withheld by the applicant had been disclosed); *Nycomed U.S. Inc. v. Glenmark Generics, Ltd.*, No. 08-CV-5023 (CBA)(RLM), 2010 WL 1257803, at \*14 (E.D.N.Y. Mar. 26, 2010) (granting defendant's motion to amend regarding inequitable conduct defense and counterclaim and finding, pre-

Second, Wyeth asserts that regardless of the representations it made to the PTO regarding the '277 reference and observational data from tigecycline solutions, "[t]he Examiner admittedly had all the relevant data and was free to disregard [Wyeth's] interpretation of it and draw his own conclusions." (D.I. 65 at 12) Although Wyeth describes this as indicating a failure to sufficiently allege but-for materiality, (*id.*), its claim is more accurately framed as an assertion that the alleged misrepresentations are not actually misrepresentations at all. This argument hinges on Wyeth's contention that "[t]he Federal Circuit has long held that merely presenting arguments and interpretations concerning a reference that was in front of the Examiner does not constitute an actionable misrepresentation." (D.I. 70 at 6 (citing cases)) That line of case law generally stands for the proposition that, to the extent that an applicant's alleged misrepresentations consist solely of arguments to the Examiner that are not unreasonable interpretations or demonstrably false, such statements do not amount to "misrepresentations" that give rise to an inequitable conduct claim. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007) (cited in D.I. 70 at 6); *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) (cited in D.I. 70 at 6); *Genzyme Corp. v. Transkaryotic Therapies, Inc.*, No. 00-677, 2004 U.S. Dist. LEXIS 19250, at \*7 (D. Del. Sept. 27, 2004) (cited in D.I. 70 at 5).

Sandoz counters that Wyeth's argument as to the alleged misstatements about the '277 reference "misses the point . . . [because] [t]he conduct of the applicants' representatives was not just zealous advocacy; it was a misleading characterization of a key reference." (D.I. 68 at 13)

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*Therasense*, that defendant's allegations of false representations to PTO were "*highly material*" because they were submitted to overcome the Examiner's rejection of application on obviousness grounds, and because in issuing a Notice of Allowance, the Examiner "expressly cited [plaintiffs] arguments" concerning the representations at issue).

Sandoz also highlights its allegation that "Mr. Ofslager withheld not the data itself but material information relating to the data, e.g., the error rate associated with the data, alternative explanations for the data, and inconsistencies in the data that draw into question its reliability (if one knows what to look for). . . . The Examiner did not have this information and had no way of independently learning it." (*Id.* at 12–13) In support, Sandoz cites an alternative line of case law establishing that although "an attorney is free to argue vigorously in favor of patentability without being subject to accusations of inequitable conduct, the law prohibits genuine misrepresentations of material fact." (*Id.* at 13 (citing *Ring Plus, Inc. v. Cingular Wireless Corp.*, 614 F.3d 1354, 1360–61 (Fed. Cir. 2010)))<sup>9</sup>

Wyeth's claim thus requires the Court to assess whether, accepting the well-pleaded facts of the inequitable conduct defense as true, and viewing those facts in the light most favorable to Sandoz, the Court can reasonably infer that Wyeth's statements crossed the line from permissible advocacy to impermissible misrepresentation. As an initial matter, the Court agrees with Sandoz that Wyeth is not relieved of responsibility for any alleged misstatements simply because the '277 reference and the stabilization data were before the PTO. It is not possible for a patent applicant to misrepresent the teachings of the prior art unless that material is before the PTO in the first place. *Cf. Ring Plus*, 614 F.3d at 1360 (upholding district court's finding that a person of skill in the art would have understood two prior art references to disclose software-based algorithms, and that because applicants had identified these two references to the Examiner and claimed that

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<sup>9</sup> See also *Rothman v. Target Corp.*, 556 F.3d 1310, 1328 (Fed. Cir. 2009) (noting that although an attorney may vigorously argue in favor of patentability without being subject to allegations of inequitable conduct, "the law prohibits genuine misrepresentations of material fact"); *VDF FutureCeuticals, Inc.*, 2011 WL 6820122 at \*6 (noting that "not all arguments by attorneys are shielded from liability for inequitable conduct").

these references did not propose software-based systems, these statements amounted to material misrepresentations). To countenance Wyeth's approach would create a perverse incentive, where applicants would be free to falsely characterize such documents, but then claim immunity from a later charge of inequitable conduct because the mischaracterized material was before the PTO.

Moreover, this Court recently affirmed the principle that attorney arguments can give rise to an actionable claim of inequitable conduct.<sup>10</sup> In *Southco, Inc. v. Penn Eng'g & Mfg. Corp.*, 768 F. Supp. 2d 715 (D. Del. 2011), this Court denied a motion to dismiss an inequitable conduct claim that was based, at least in part, on alleged misrepresentations that the patentee's counsel made during reexamination proceedings. *Id.* at 723–24. In *Southco*, the accused infringer requested reexamination of the asserted patent in light of a prior art fastener that was found in a catalog, referred to as the "Huck reference." *Id.* at 721–22. The patentee argued to the PTO that the claims-at-issue were nonetheless patentable for two reasons: (1) the Huck reference failed to "disclose a 'rigid connection' between the head of the screw and the knob" of the depicted fastener, as required by the patented claims; and (2) the Huck reference likewise did not show the "protrusions" required by the claimed fastener. *Id.* at 722. In seeking to dismiss and strike the counterclaim and affirmative defense of inequitable conduct in later litigation, the *Southco* plaintiff asserted (just as Wyeth has here) that the patentee's statements to the Examiner were simply "arguments of counsel and, therefore, they cannot be considered misrepresentations." *Id.* This Court rejected that proposition, and instead found that the alleged misrepresentations, even

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<sup>10</sup> All three of the cases that Wyeth cites in support of its argument that the alleged misrepresentations do not give rise to even a plausible inequitable conduct claim are of limited utility, as all of them involved a district court decision as to the sufficiency of an inequitable conduct claim at or after the summary judgment stage. (D.I. 70 at 5–6 (citing cases))

if categorized as mere "attorney argument," were "sufficient to satisfy the requirements of [Rule 9(b)]." *Id.* at 723. In doing so, it noted that defendant's allegations were, in part, "that Southco's arguments to the Examiner amounted to material misrepresentations because Southco knew its arguments were factually and patently false" given its pre-existing knowledge of the actual fastener. *Id.*<sup>11</sup> Thus, *Southco* demonstrates that a claim based upon allegedly false and misleading statements to the PTO regarding a prior art reference (or other information submitted to the PTO, such as experimental data) can survive the pleading stage (assuming that the other elements of the inequitable conduct defense are sufficiently pled).

In line with the decision in *Southco*, the Court finds that at this stage, Sandoz has alleged sufficient facts to support the reasonable inference that Wyeth made actionable misrepresentations to the Examiner. The alleged misrepresentations here concern not only knowledge of this particular industry, but also relate to Wyeth's internal testing procedures and protocols. This is precisely the sort of information that Mr. Ofslager was uniquely qualified to characterize and explain, which is what allegedly allowed him to "deceive" the Examiner by failing to do so accurately. (D.I. 62 at 16, ¶ 30) Moreover, at least with regard to Mr. Ofslager's alleged failure to disclose to the Examiner certain significant error rates, Sandoz appears to assert that this data was never provided by Wyeth to the Examiner in any form, which would have required the Examiner to rely even more significantly on Mr. Ofslager's representations. (D.I. 62 at 11, ¶ 16 ("Mr. Ofslager . . . never explained to the Examiner either the error rate in these

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<sup>11</sup> See also *Elan Corp., PLC v. Teva Pharms. USA, Inc.*, Civ. No. 07-552-SLR, 2008 WL 623506, at \*1 (D. Del. Mar. 7, 2008) (denying plaintiff's motion to dismiss inequitable conduct claims and to strike related affirmative defenses in light of allegations that arguments made to patent examiner involved intentional falsehoods about a material reference, and did not simply constitute permissible attorney argument).

figures or its significance to his conclusions.")) Taking these facts as true, as the Court must at this stage, it is at least plausible that the alleged misrepresentations traversed the line from mere argument to actionable falsehoods.

## **2. Intent Prong—Specific Intent to Deceive the PTO**

In its opening brief, Wyeth asserts that Sandoz's inequitable conduct defense should also be dismissed for failure to allege a plausible claim of deceptive intent. Wyeth states that Sandoz has failed to meet its burden pursuant to the intent prong for two primary reasons.

First, Wyeth claims that "Sandoz [did] not allege facts from which the Court could conclude that the 'single most reasonable inference' to be drawn is that Wyeth intended to deceive the PTO" because "a conclusion that the named individuals acted innocently without any intent to deceive the PTO *is at least as plausible*, if not more so, than a conclusion of intent to deceive." (D.I. 65 at 10 (emphasis added)) As noted above, this argument was largely premised on the view that Sandoz could survive a motion to dismiss if and only if it offered evidence that deceptive intent was the single most reasonable inference to be drawn from the facts pled. Yet Wyeth withdrew that assertion at oral argument, (D.I. 85 at 9–10), and the Court has now concluded that the "single most reasonable inference" analysis was not meant to be grafted onto the standard for analysis of the sufficiency of pleadings. Yet it is notable that in its briefing, even Wyeth appeared to concede that a "conclusion of intent to deceive" is "at least" one "plausible" inference based on the facts as pled. (D.I. 65 at 10)

Second, Wyeth asserts that given the alleged "objective indicators of candor and good faith" inherent in Sandoz's pleading, and the fact that the alleged misrepresentations are "nothing more than the typical exchanges between an applicant and the PTO," Sandoz has failed to



plausibly allege deceptive intent. (*Id.* at 10–11) Wyeth expands on this argument in its Reply Brief, asserting that Sandoz failed to cite any evidence concerning when Mr. Ofslager became aware of any alleged data discrepancies, whether he even considered them when presenting the data at issue to the Examiner, or whether in doing so, Mr. Ofslager "deliberately set out to deceive." (D.I. 70 at 4) Wyeth claims Sandoz's allegations thus amount to "an unsupported theory of intent." (*Id.*)

Sandoz responds to Wyeth's arguments first by cataloguing the alleged inaccuracies and inconsistencies in the tigecycline stabilization data that were submitted to and relied upon by the PTO, noting that "the accuracy of these measurements, and their comparability between experiments, was the entire premise of Mr. Ofslager's assertion of unexpected results." (D.I. 68 at 14) Sandoz alleges that this "premise" is fatally undermined by, *inter alia*, the unreported error rate and data (that was absent from Mr. Ofslager's "incomplete" presentation) showing tigecycline epimerization inexplicably decreasing over time in certain experiments. (D.I. 62 at 11–14) Given that "a person of extraordinary skill such as Mr. Ofslager would appreciate that these inconsistencies raise serious doubts about the accuracy and reliability of the methods used" by Wyeth to assess tigecycline, Sandoz argues that Mr. Ofslager's representations were meant to deliberately mislead the PTO. (D.I. 68 at 16)

The Court finds that Sandoz has pled sufficient facts, with sufficient particularity, to give rise to a reasonable inference that Wyeth's representatives deliberately acted to deceive the PTO during the prosecution of the '828 patent. Sandoz alleges that Wyeth engaged in a multi-faceted strategy to deceive the PTO by convincing the Examiner that the claimed invention, which exposes tigecycline to acidic conditions in combination with lactose, results in a much more

stable solution than the prior formulations of tigecycline. (D.I. 62 at 17, ¶ 32) By way of example, Sandoz asserts that Mr. Ofslager offered numerous test results to the PTO that compared "First Generation Tigecycline" (without hydrochloric acid or lactose) to "Second Generation Tigecycline" (containing both of those elements). (*Id.* at 15, ¶ 28; ex. 1 at ¶¶ 8–9) Mr. Ofslager interpreted this data, which showed that the purity of tigecycline was reduced by more than 2% in First Generation Tigecycline as compared to Second Generation Tigecycline, and represented that "Second Generation Tigecycline possesses a *significantly greater stability* [from prior formulations without the elements claimed in the '828 patent] in both lyophilized and reconstituted forms." (*Id.*, ex. 1 at ¶ 36 (emphasis added)) Yet Sandoz contends that Mr. Ofslager did not tell the Examiner that the error rate in these measurements was about 2%, nor that other data in the submitted materials contained results so anomalous as to render them effectively unreliable, thus creating an incomplete and misleading picture. (*Id.* at 15–16, ¶ 29)

Additionally, Sandoz repeatedly states that Mr. Ofslager made these false and misleading representation in a "deceptive" fashion—in essence, Sandoz alleges that Mr. Ofslager knew about the existence of this problematic data but made a calculated, deliberate decision to conceal it in his presentations to the Examiner. (*Id.* at 16, ¶ 30 ("As with his characterization of the data from the '330 application, Mr. Ofslager presented the data from the stability reports in a deceptive way. . . . Thus, the '828 patent would not have been issued but for Mr. Ofslager's deceptive and erroneous representations to the Patent Office.")) Assuming that Sandoz's allegations are accurate, as I must at this stage, then those allegations give rise to the plausible claim that Mr. Ofslager's presentation was designed to mislead the Examiner into issuing the '828 patent on a faulty premise (of unexpected results). *Accord Pollin Patent Licensing, LLC*, 2011 WL 5118891

at \*4 (granting motion for leave to amend to assert inequitable conduct claim and finding allegation of deceptive intent was sufficient, where counterclaimant alleged that withheld information would have been material to the PTO's examination and was known to applicant).

Moreover, although Wyeth claims that "Sandoz does not present any evidence concerning when Mr. Ofslager became aware of the[] alleged 'discrepancies'" in tigecycline data or whether he even considered them when presenting data to the Examiner (D.I. 70 at 4), the Court finds that the allegations give rise to that plausible inference. Mr. Ofslager represented that all of the "facts presented in [his] Declaration" were "of [his] own knowledge" and that he had read, was familiar with, and understood Wyeth's patent application. (D.I. 62, ex. 1 at ¶¶ 9–11 & pg. 10) More significantly, Mr. Ofslager was the individual who developed the manufacturing process for the current version of Tygacil® made by Wyeth, which "contains lactose monohydrate as a diluent/stabilizer and hydrochloric acid as pH adjustment." (*Id.*, ex. 1 at ¶ 8) He not only oversaw this process, but developed or co-developed several other drugs, and is the inventor of multiple U.S. patents and applications. (*Id.*, ex. 1 at ¶¶ 6–7) Given Mr. Ofslager's experience, his direct oversight of this process, and his statements to the Examiner, it is reasonable to infer, at this stage, that he was familiar with the testing protocols he cited in his declaration (and that were included in the '828 patent specification), as well as the contrary data referenced by Sandoz.

In its briefs, Wyeth cites only a single instance of a case in this Court where an inequitable conduct claim was disallowed in its entirety at the pleading stage due to the failure to adequately allege scienter: *Softview LLC v. Apple Inc.*, No. 10–389–LPS, 2011 WL 4571793 (D. Del. Sept. 30, 2011). *Softview* is distinguishable from the present facts, most notably because unlike the many deliberate misrepresentations regarding stabilization data alleged in the instant

case, the *Softview* counterclaim focused only on a "mere disagreement" over what constituted "new matter" in a patent application. *Id.* at \*1. Similarly, Wyeth cites *Fred Hutchinson Cancer Research Ctr. v. BioPet Vet Lab, Inc.*, Civil Action No. 2:10cv616, 2011 WL 2551002 (E.D. Va. June 27, 2011), another case in which a district court disallowed an inequitable conduct claim at the pleading stage on grounds that insufficient evidence of deliberate deception was pled. However, the claim at issue in *Fred Hutchinson* involved only "curs[o]ry allegations" that the inventors of a patent were aware of undisclosed prior art. *Id.* at \*3. Those cursory allegations pale in comparison to the lengthy factual recitation in Sandoz's pleading here, which alleges misrepresentations by Mr. Ofslager and others acting on Wyeth's behalf, regarding data that they repeatedly and affirmatively brought to the PTO's attention.

At oral argument, Wyeth also cited an additional, unpublished district court decision granting a motion to dismiss inequitable conduct allegations—*Human Genome Sciences, Inc. v. Genentech, Inc.*, Case No. 2:11-cv-6519-MRP (JEMx) (C.D. Cal. Dec. 9, 2011) (slip op.) Wyeth argued that because the facts in *Genentech* are closely analogous to those at issue here, the Court should similarly dismiss Sandoz's inequitable conduct defense. (D.I. 85 at 11)

Although the *Genentech* inequitable conduct defense included many different elements, two particular allegations are most relevant here: (1) alleged misrepresentation of a prior art reference; and (2) alleged misrepresentation of experimental data. *Genentech*, slip op. at 8–10. In *Genentech*, the defendants alleged that one of Genentech's scientists stated that the patent application-at-issue and a series of prior art references were closely related. *Id.* at 8. Genentech's prosecution counsel later represented to the PTO that one of those same prior art references "was 'irrelevant to the claims of [the patent application].'" *Id.* at 8–9. The *Genentech* court found that

these allegations were insufficient to give rise to a reasonable inference of deceptive intent. *Id.* at 9. These allegations bear little resemblance to those at issue in this case. Sandoz's argument is that Wyeth's representatives asserted that the prior art, as exemplified by the '277 reference, did not disclose a stabilization mechanism that would work for tigecycline. (D.I. 62 at 9, ¶ 10; 10, ¶ 12) Sandoz's arguments are not exclusively directed to the '277 reference itself, but rather concern the real-world applications of the biochemical mechanisms disclosed in that reference. (*Id.*) If anything, this portion of *Genentech* simply stands for the proposition that conflicting statements from party-representatives will not alone be sufficient to assert a plausible claim. That proposition is inapplicable to the facts as pled by Sandoz.

The *Genentech* defendants also pointed to "one of the inventor's statements to the PTO that the experiment in the specification had resulted in reactions 'significantly higher than the background,' whereas that inventor had previously said[,] in a private letter to a colleague, that the data in the application was 'barely measurable above background.'" *Genentech*, slip op. at 10. The *Genentech* court determined that "[a]ny number of reasons could exist for that contradiction—the inventor could have made a mistake in that letter or he could have changed his mind about how to read the data." *Id.* Although there could well be an innocent explanation for the conduct described in Sandoz's inequitable conduct defense, under *Exergen*, that is by no means the *only* reasonable inference to be drawn here. Moreover, in this case, the alleged contradictions go to the heart of patentability. The Examiner made clear that the '330 application was rejected because the stability of the claimed invention offered only "minimal" advantages over the prior art. (D.I. 62 at 8, ¶ 8) Thus, Wyeth's only recourse to obtain the '828 patent was to assert that something more than a "minimal" increase in stability was observed in the claimed

combination, even if the experimental data was inconsistent with that conclusion. There is no evidence that the contradiction at issue in *Genentech* was so central to patentability, or that there was such a motive to overstate the effectiveness of the invention. Thus, the cases cited by Wyeth do not alter the Court's conclusion as to this issue.

#### **IV. CONCLUSION**

The Federal Circuit has expressed an unequivocal desire to reign in the proliferation of inequitable conduct claims, which have "increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality." *Therasense*, 649 F.3d at 1290. However, that effort must be balanced against the fact that "honesty at the PTO is essential," and thus inequitable conduct claims remain viable as a general matter, even when they are not based solely on affirmative acts of egregious misconduct. *Id.* at 1290, 1292. While Sandoz faces a more difficult task of proving inequitable conduct in light of the Federal Circuit's recent precedent, it has provided a lengthy recitation of facts that give rise to a reasonable inference that Wyeth misrepresented material information with the intent to deceive the PTO. Thus, I recommend that the Court DENY Plaintiffs' motion.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order In Non-Pro Se Matters For

Objections Filed Under Fed. R. Civ. P. 72, dated November 16, 2009, a copy of which is available on the Court's website, <http://www.ded.uscourts.gov/StandingOrdersMain.htm>.

Because this Report & Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single jointly proposed redacted version of the Report & Recommendation. Such redacted version shall be submitted no later than **February 10, 2012** for review by the Court. The Court will subsequently issue a publicly-available version of its Report & Recommendation.

Dated: February 3, 2012

  
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Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE